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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | | |
|---|-------------|----------------------|---------------------|----------------------|--|--|
| 10/614,037 | 07/08/2003 | Manfred Reiter | 14693-0195 | 9074 | | |
| 61263 | 7590 | 02/04/2009 | EXAMINER | | | |
| PROSKAUER ROSE LLP 1001 PENNSYLVANIA AVE, N.W., SUITE 400 SOUTH WASHINGTON, DC 20004 | | | | VOGEL, NANCY TREPTOW | | |
| ART UNIT | | PAPER NUMBER | | | | |
| 1636 | | | | | | |
| MAIL DATE | | DELIVERY MODE | | | | |
| 02/04/2009 | | PAPER | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/614,037 | REITER ET AL. | |
| | Examiner | Art Unit | |
| | NANCY VOGEL | 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 21 January 2009.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 34-36 and 46-66 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 34-36, 46-66 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/21/09 has been entered.

Claims 34-36 and 46-66 are pending in the case.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34-36, 46-66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for growth of VERO cells in the medium specified in the examples, does not reasonably provide enablement for a method for producing an immunogenic composition comprising a virus or a virus antigen comprising providing a culture of any cell , or any of a list of the cell types set forth in claims 64-66, 65 and 56-58, grown in any animal protein free medium comprising soy and yeast hydrolysate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

This rejection is maintained essentially for the reasons made of record in the previous Office action, mailed 8/19/08. Applicant's arguments filed 1/21/09 have been considered but have not been found convincing.

Applicants have argued that it would not require undue experimentation to practice the invention throughout its scope in light of methods disclosed in the specification and based on what is known in the art. Applicants argue that the reference Shubiya (US 6406909) is improperly cited since Shibuya did not use the same medium as recited in the claimed invention, since it does not exclude Insulin Human Recombinant, and may include animal proteins produced with recombinant techniques. Applicant argues that the instant claimed method avoids animal proteins and therefore Shibuya is not relevant.

However, it is maintained that Shibuya is relevant for the teaching that it cannot be easily predicted whether any particular culture medium would support growth of any particular cell type, and that even when culture medium is supplemented by recombinant animal products, it cannot be predicted whether growth of a particular cell type will be supported. Furthermore, applicant's arguments that the experimentation required to practice the invention for any of the cell types encompassed by the claims, is not found convincing. It is maintained that merely setting forth a few examples for growth of one cell type, using one type of culture medium, does not provide support for the growth of any cell type, using any type of culture medium with the only requirement being that yeast and soy hydrolysates are present. There is no predictability to guide one to the choice of a particular cell culture medium, which, when supplied with yeast

and soy hydrolysates, would successfully support the culture of any particular cell type. While the fact that the specification only discloses the growth of VERO cells in one particular culture medium does not in itself show that the claimed method is not enabled, the fact that one of skill in the art cannot predict whether other cell types would have the same culture requirements, and the fact that undue experimentation such as the choice of virtually infinite numbers of possible components and concentrations thereof, for a cell culture medium, would be required, show that the specification does not provide an enabling disclosure to support the scope of the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34-36, and 46-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Price et al. (WO 98/15614) in view of Kistner et al. (US Patent 5,753,489), Luderer et al. (US P patent 4282315), Gauri et al. (US Patent 4,322,404) and Quest International Product Information, Norwich NY, 1995, and Sheffield Pharma Ingredients, Cell Nutrition, Hydrolyzed Proteins & Yeast Extracts, Technical Manual (all previously cited).

This rejection is maintained essentially for the reasons made of record in the previous Office action, mailed 8/19/08.

Applicant's arguments filed 1/21/09 have been considered but have not been found convincing.

Applicants have argued that Price et al. does not disclose an animal protein free medium and that the examiner is improperly using hindsight reconstruction of the prior art. Applicants argue that the reference teaches the "substitution" for animal products by enzymatic digests of yeast and soy cells, and that this does not constitute a teaching of an animal product free culture medium. However, it is maintained that when one substitutes animal products with soy and yeast cell hydrolysates, one arrives at an animal free culture medium. The fact that all such animal products are substituted with the disclosed soy and yeast cell hydrolysates, results in an animal free cell culture medium, is not excluded by the reference. Therefore, applicant's arguments are not found convincing.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY VOGEL whose telephone number is (571)272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/
Primary Examiner, Art Unit 1636

NV
2/2/09